UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION _____ THIS DOCUMENT RELATES TO: *Brady, et al. v. UniFirst Corporation., et al.* Docket No. 1:14-cv-10284-RWZ	MDL No. 1:13-md-2419-RWZ

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO CPM DEFENDANTS' MOTION TO DISMISS PURSUANT TO F.R.C.P. 12(b)(6).

INTRODUCTION

Since the time of the filing of the CPM Defendants[1] motion to dismiss, this Honorable Court has resolved many of the issues addressed, allowing Plaintiffs to move forward with negligence, gross negligence, failure to warn, products liability, violation of consumer protection and punitive damages claims against New Jersey and Tennessee Clinics.[2] The decision to deny the motions to dismiss these counts brought by the New Jersey and Tennessee Clinics was made when considering identical allegations set forth by all plaintiffs in the Master Complaint.[3] The Court should not deviate from its prior, well-reasoned decision[4] denying dismissal of such claims. Dismissal of Plaintiffs' negligence, gross negligence, failure to warn, products liability, violation of consumer protection and punitive damages claims should also be denied here as it

[1] Plaintiffs were recently informed by defense counsel that Cincinnati Pain Management Consultants, Ltd. is not an entity currently in existence and it is their understanding that all the assets of Cincinnati Pain Management Consultants, Ltd. were purchased by Cincinnati Pain Physicians LLC. Therefore, "CPM Defendants," "Defendants" and/or "CPM" refers collectively to Defendants Cincinnati Pain Management Consultants, Inc., Cincinnati Pain Management Consultants, Ltd., Cincinnati Pain Physicians LLC and Gururau Sudarshan, M.D.

[2] *See* Memorandum and Decision, Doc. No. 1360 (Zobel, Aug. 29, 2014) (hereinafter "Order 1360").

[3] Master Complaint against UniFirst and Clinic-Related Defendants, Dkt. No. 545, as amended by Dkt. No. 832, hereinafter "Master Complaint" or "Complaint."

[4] In light of the Court's dismissal of the Battery, Agency and Conspiracy claims, Plaintiffs will concede those claims against the CPM Defendants, reserving the right to re-allege the claims upon discovery of additional information in support of them. *See* Order 1360.

relates to the CPM Defendants.

It is undisputed that the widespread outbreak of fungal meningitis, which gave rise to this multi-district litigation, was caused by contaminated preservative free methlyprednisolone acetate ("MPA") compounded by New England Compounding Center, Inc. ("NECC") being administered to patients at over 70 pain clinics, orthopedic practices and hospitals,[5] including the CPM Defendants. Liability extends to the health care providers and facilities that purchased the contaminated products and distributed it to their patients. Despite extensive guidelines setting forth doctors' and clinics' responsibilities when outsourcing risky compounded drugs, the CPM Defendants failed to perform any due diligence. Instead, the CPM Defendants mail ordered thousands of vials of prescription preservative free MPA from NECC without any reasonable effort to assess and evaluate NECC's ability to aseptically make, package and dispense preservative free MPA.

The Master Complaint filed by the Plaintiffs' Steering Committee on November 5, 2013 and the Long Form Complaint[6] filed by the responding Plaintiffs on December 18, 2013, both incorporated by reference through the filing of the Short Form Complaint in the above-captioned related action, set forth in great detail the reasons why these healthcare providers, including the CPM Defendants, share responsibility for Plaintiffs' injuries and harm. Without CPM's negligent and reckless conduct in mail ordering and purchasing contaminated steroids and administering them to patients without performing any due diligence, Plaintiff would not have received contaminated MPA in his spinal column causing him to suffer serious injuries. The

[5] *See* CDC, Multistate Fungal Meningitis Outbreak Investigation, http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html (Visited March 2014); *see also* FDA, Multistate outbreak of fungal meningitis and other infections, http://www.fda.gov/%20Drugs/DrugSafety/FungalMeningitis/default.htm; Smith, Rachel M., et al., *Fungal Infections Associated with Contaminated Methylprednisolone Injections*, N Engl J Med 2013; 369:1598-1609 (Oct. 24, 2013).

[6] Long Form Complaint against CPM Defendants and NECC Related Defendants, 1:14-cv-10284 Dkt. No. 1.

factual and legal allegations in the Master Complaint concerning the "Clinic Related Defendants"[7] are thorough, well-pleaded, and sufficiently state claims upon which relief can be granted. Plaintiffs plead an actionable multi-count case that the CPM Defendants, without due, proper and necessary qualification of NECC's competence and ability, acquired and administered adulterated preservative free MPA from NECC, and, importantly, did so by submitting prescriptions to NECC that flagrantly violated Massachusetts' controlled substances law[8], Massachusetts' consumer protection law[9], Ohio Products Liability Law[10], Ohio's controlled substances law[11] and Ohio's consumer protection law[12].

The Master Complaint and Long Form Complaint are lengthy and describe in a detailed manner how the CPM Defendants' conduct contributed to the outbreak. For example, the Complaint alleges that Defendants failed to exercise reasonable care to ensure that the drugs they purchased and administered to Plaintiff were manufactured in compliance with applicable pharmaceutical laws. Master Compl., ¶ 234(a). The Complaint alleges that the CPM Defendants failed to perform the necessary due diligence to determine the safety and quality of NECC's drugs and failed to determine if NECC could properly provide sterile, preservative free drugs for administration to patients. Master Compl., ¶ 234(d). The Complaint also states that the CPM Defendants failed to conduct sufficient due diligence to determine whether NECC was a reputable and safe supplier of sterile injectable compounds and the Complaint asserts that CPM

[7] The Master Complaint lists a number of facilities that received recalled lots of MPA from NECC. Those hospitals, clinics, healthcare facilities, and their physicians, staff, agents, and employees are referred to in the Master Complaint collectively as the "Clinic Related Defendants." Master Compl. ¶¶ 22-23. The CPM Defendants are included in this defined term. *Id*. at 22. In addition, because the Master Complaint was adopted and incorporated by reference in each of the above-captioned related actions, the term "Clinic Related Defendants" has come to include and apply to the CPM Defendants.
[8] MGL Ch. 94C §1 et seq.
[9] MGL Ch. 93A.
[10] O.R.C. §§ 2307.74, 2307.76, 2307.77, et seq.
[11] Ohio Admin. Code 4729-5-30(B) (requiring a prescription to contain the patients full name and residential address).
[12] O.R.C. §1345.01 et seq. and O.A.C. §§ 109:4-3-01 et seq.

purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions as required by law. Master Compl., ¶ 234(j)(q). In addition, the Master Complaint avers that as a result of CPM's conduct, Plaintiff, Mr. Brady, was administered contaminated products causing serious injuries. Master Compl., ¶¶ 270, 271, 298, 303, 355.

Defendants filed the instant Rule 12(b)(6) Motion to Dismiss seeking dismissal of the following causes of action set forth in the Short Form Complaint against the CPM Defendants: Count III – Negligence and Gross Negligence; Count IV – Violation of the Ohio Consumer Protection Laws; Count VII – Battery; Count VIII – Failure to Warn; Count IX – Ohio Product Liability Claims; Count X – Agency; Count XI – Civil Conspiracy; Count XIII – Loss of Consortium; and Count XIV – Punitive Damages.[13] However, for the reasons below, Plaintiffs have more than adequately stated their claims and CPM Defendants' Motion to Dismiss should be denied.

STANDARD OF REVIEW

In deciding a motion to dismiss, "a court does not rule on the evidentiary sufficiency of a complaint, only on whether its factual and legal assertions allege 'a plausible entitlement to relief.'" *Balerna v. Gilberti*, CIV.A. 09-10075-RGS, 2010 WL 4878286, at *4 (D. Mass. Nov. 24, 2010); (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007)). In considering a motion to dismiss, the court should "treat as true all well-pleaded facts, viewing those facts in the light most favorable to the plaintiff, and drawing all reasonable inferences therefrom for [plaintiff]." *Knowlton v. Shaw*, 704 F.3d 1, 3 (1st Cir. 2013) (*citing Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir.2008)). Under *Twombly*, a complaint need only allege "enough factual matter (taken as true) to suggest" the validity of the claim. *Twombly*, 550 U.S. at 557. "To

[13] Typographical errors were made in Counts IV and IX of the Short Form Complaint where Illinois was written instead of Ohio. To the extent that this Court deems it necessary, Plaintiffs would request the opportunity to amend the Short Form Complaint to remedy this nonprejudicial error.

justify a dismissal on any Civ. R. 12(B)(6) motion, the court must find beyond doubt from the complaint that the plaintiffs can prove no set of facts entitling them to relief." *Saylor v. Providence Hosp.*, 113 Ohio App. 3d 1, 3-4, 680 N.E.2d 193, 194-95 (1996).

LAW AND ARGUMENT

I. Plaintiffs Reserve the Right to Argue Massachusetts Law Rather than Ohio Law Should Be Applied to the Instant Case

Plaintiffs do not concede that Ohio substantive law is applicable in the instant case, and importantly, the CPM Defendants fail to make any choice of law analysis whatsoever to support their contention that Ohio law applies to Plaintiffs' claims.[14] In raising this issue, Plaintiffs reserve the right to fully brief the choice of law analysis at a later date. In sum, Plaintiffs will argue that the Commonwealth of Massachusetts has a significant interest in the litigation so as to make the application of Massachusetts substantive law appropriate. Plaintiffs contend that Massachusetts has a more significant interest than Ohio because the majority of the wrongful conduct, at the heart of this litigation, took place in Massachusetts. For example: the compounding facility at the source of this litigation was located in Massachusetts, the MPA was actually compounded in Massachusetts, the contamination took place in Massachusetts, Defendants intentionally placed bulk orders to the facility they knew was regulated by the laws of Massachusetts not the FDA, Defendants had the drugs shipped from Massachusetts, Defendants paid for the contaminated MPA and payment was processed in Massachusetts and Defendants did nothing to verify or investigate the safety measures taken by the facility. Consequently, since the majority of the wrongful conduct took place in Massachusetts, this Court

[14] In their Motion to Dismiss, Defendants present no support for their contention that Ohio law will be applicable, rather than Massachusetts substantive law.

should apply Massachusetts substantive law to the instant case.[15] Nonetheless, Plaintiffs' complaint meets the pleading requirements of both Massachusetts and Ohio law and Plaintiffs address Ohio law herein in response to the CPM Defendants' motion.

II. Plaintiffs Sufficiently Allege Negligence and Gross Negligence

A. Plaintiffs Pled Sufficient Allegations of Duty

The CPM Defendants cannot deny they owed Plaintiff, Mr. Brady, a fiduciary duty, based on special trust and confidence, to exercise good faith and the requisite degree of care and skill in their treatment. *Turner v. Children's Hosp., Inc.*, 76 Ohio App. 3d 541, 555, 602 N.E.2d 423, 431-32 (1991) (*citation omitted*); *see also Tracy v. Merrell Dow Pharm., Inc.*, 58 Ohio St. 3d 147, 150, 569 N.E.2d 875, 879 (1991) (*citations omitted*). Under Ohio law, the CPM Defendants' had a duty to employ reasonable care and diligence in the exercise of skill and knowledge within the medical profession. *Turner v. Children's Hosp., Inc.*, 76 Ohio App. 3d 541, 555, 602 N.E.2d 423, 431-32 (1991). Thus, the CPM Defendants are charged with, at minimum, the duty to act "reasonably" which Plaintiffs have adequately alleged in their complaint. Master Compl., ¶¶ 152, 227-231.

While the CPM Defendants do not dispute that they owed Plaintiffs a duty or that duty

[15] *Boston Hides & Furs, Ltd. v. Sumitomo Bank, Ltd.*, 870 F. Supp. 1153, 1166-67 (D. Mass. 1994) (In analyzing a choice of law issue, "[Massachusetts] courts preferred either a "place of conduct" analysis, focusing on the location of the alleged conduct which violated Chapter 93A (internal citation omitted) or a "functional approach" which "responds to the statutory concern with commercial conduct in Massachusetts."); *Auto Europe, LLC v. Connecticut Indem. Co.*, 321 F.3d 60, 66 (1st Cir. 2003) (Illinois plaintiffs filed a consumer fraud suit against an automobile insurance company and that company's insurer refused to defend it in the pending suit. The court held that even though plaintiffs were located in Illinois and the insurer was located in Florida, Maine law was applicable because the insured was located in Maine and the underlying lawsuit was based on wrongful conduct allegedly committed in Maine.); *Tingley Sys., Inc. v. CSC Consulting, Inc.*, 152 F. Supp. 2d 95, 115 (D. Mass. 2001) (In a misappropriation of trade secret claim, the court found the place of injury did not play an important role and, "Instead, the principal location of the defendant's conduct is the contact that will usually be given the greatest weight in determining the state whose local law determines the rights and liabilities that arise from…the misappropriation of trade values." *Id.* quoting *Restatement (Second) of Conflict of Laws,* § 145, Comment (f) (1971).); See also *Data Cash Systems, Inc. v. JS & A Group, Inc.*, 480 F.Supp. 1063, 1071 (N.D.Ill.1979), *aff'd*, 628 F.2d 1038 (7th Cir.1980) ("…principal location of the defendant's conduct is the contact that is usually given the greatest weight in determining" the choice of law in an unfair competition claim).

was sufficiently pled, they appear to take issue with Plaintiffs' allegations as to the standard of care imposed by their duty. In particular, the CPM Defendants complain about the use of the words "due diligence" to describe their duty but fail to establish how "due diligence" is any different from their acknowledged duty to act with "reasonable care and diligence."[16] CPM Brief, p. 4-6.

The CPM Defendants also complain about Plaintiffs' allegations related to the American Society of Health-System Pharmacy Guidelines on Outsourcing Sterile Compounding Services ("ASHP Guidelines"), claiming that they do not establish any duty under Ohio law. While the ASHP Guidelines are not regulations, allegations related to them certainly may be considered and are relevant to establishing the parameters of that duty. *See Keeton v. Telemedia Co. of S. Ohio*, 98 Ohio App. 3d 405, 410, 648 N.E.2d 856, 859 (1994) (holding that a reasonable jury could conclude that defendant breached its duty to use due care by failing to follow industry guidelines). Additionally, the CPM Defendants ignore that Ohio's Board of Pharmacy regulations, similar to Massachusetts, places a duty to properly prescribe drugs on both the pharmacy and the prescriber, which includes listing the patient name and addresses and also prohibits bulk ordering from compounding pharmacies.[17] *See* Ohio Admin. Code 4729-5-30.

It is clear that the CPM Defendants owed Plaintiffs a duty to exercise reasonable care, and that failure to follow the ASHP Guidelines and Ohio law, is at the very least, evidence that they breached their duty. Moreover, it is well-established that the allegations set forth by Plaintiffs which allege that the exercise of due care requires compliance with the ASHP

[16] Such pointless arguments over semantics should not be engaged by the Court. Moreover, Plaintiffs' allegations related to the CPM Defendants' duty set forth claims beyond just the allegations of "due diligence" owed to the Plaintiff, but those seem to be entirely ignored by the CPM Defendants.

[17] Ohio Adm.Code 4731-21-02 has also codified rules for physicians treating intractable pain. In part, the standard identified requires, "formulating and documenting an individualized treatment plan specifying the medical justification of the treatment via the utilization of prescription drugs on a protracted basis or in combinations or amounts that may be inappropriate for treating other medical conditions." *Nucklos v. State Med. Bd. of Ohio*, No. 09AP-406, 2010-Ohio-2973, slip op. at 6 (Ohio Ct. Ap. June 29, 2010) (citing Ohio Adm. Code 4731-21-02(A)).

Guidelines are to be taken in the light most favorable to Plaintiffs. *See* Master Compl., ¶¶ 191-193, 234(e), 249, 255(b). Furthermore, Plaintiffs' experts, at a more appropriate, less premature time, will testify similarly. Lastly, the CPM Defendants cannot deny that they had a duty to their patient, Mr. Brady, to exercise reasonable care in their treatment of him. Because the Plaintiffs have sufficiently set forth allegations sufficient to establish plausible entitlement to relief, the CPM Defendants' motion should be denied.

B. Plaintiffs Have Sufficiently Alleged Causation

The Plaintiffs have sufficiently set forth causation allegations establishing plausible entitlement to relief. In making their unsubstantiated arguments, the CPM Defendants completely ignore over thirteen pages in the Master Complaint that allege numerous negligent acts and omissions by the CPM Defendants and that those acts caused Plaintiff to be injected with contaminated drugs from NECC that resulted in his injuries. *See* Master Compl., ¶¶ 151-206, 226-242. Consequently, when viewing more than just the one selective allegation referenced by the CPM Defendants, it is evident that Plaintiffs have sufficiently plead allegations to establish both factual and proximate causation. Master Compl., ¶¶ 153, 174, 189, 199, 205-206, 207-210, 236- 242.

Plaintiffs' allege that multiple wrongful acts of the CPM Defendants caused their injuries, not just bulk ordering of MPA from NECC as the CPM Defendants would like the Court to believe. Indeed, the Plaintiffs allege that the CPM Defendants were negligent in purchasing non-FDA approved preservative-free drugs, to be injected directly into Plaintiff's vulnerable central nervous system, from an unaccredited compounding facility, in bulk and under inaccurate names, and failing to perform any due diligence on NECC before purchasing, acquiring and administering its products into Plaintiff, and failing to inform him of the risks and dangers associated with MPA and spinal injections. *See* Master Compl. ¶¶ 154-155, 158-163, 165-166,

174-176, 180, 192, 199, 204, 234(a)-(q), 301-302. Furthermore, Plaintiffs have alleged that but for the CPM Defendants' negligent acts and omissions, Plaintiff, Mr. Brady, would not have been injected by the CPM Defendants with contaminated drugs resulting in injuries. *See* Master Compl., ¶¶ 153, 174, 189, 199, 205-206, 207-210, 237-242. After all, the CPM Defendants were the last party to touch the NECC contaminated product and the party responsible for actually injecting it into Plaintiff. Had they acted non-negligently, Mr. Brady never would have received the contaminated injection from NECC.

Additionally, contrary to what the CPM Defendants would like the Court to believe, courts in Ohio have held that concurrent or multiple causes can serve as the proximate cause for an injury and illness to a plaintiff. *See Czarney v. Porter*, 166 Ohio App.3d 830, 833, 853 N.E.2d 692, 693 (8th Dist. 2006) ("It is well accepted that two factors can combine to produce damage or illness, each being considered a proximate cause of the injury."); *see also State Farm Mut. Auto. Ins. Co. v. VanHoessen*, 114 Ohio App.3d 108, 112, 682 N.E.2d 1048, 1050 (1st Dist. 1996) ("An injury may have more than one proximate cause."). Therefore, the fact that NECC may also have been negligent and contributed to the Plaintiffs injuries, as alleged by the CPM Defendants, does not relieve them from liability for their own negligence that also contributed to the Plaintiffs' injuries. Plaintiffs have sufficiently set forth allegations of causation, warranting denial of the CPM Defendants' motion to dismiss.

C. Plaintiffs Have Sufficiently Alleged Gross Negligence

This Honorable Court has already denied the Tennessee Clinics' motion to dismiss the identical gross negligence count set forth in the Master Complaint that was adopted by the Plaintiffs here and in Tennessee.[18] The Court should not disturb its prior decision declining to dismiss Plaintiffs' gross negligence claim.

[18] *See* Order 1360, p. 37-38 and 63.

As it relates to this case, the Ohio Supreme Court defines "gross negligence" as the "failure to exercise any or very slight care[,]" but also recognizes that "what may be mere ordinary negligence under one class of circumstances and conditions may become gross negligence under other conditions and circumstances." *Johnson v. State*, 66 Ohio St. 59, 67, 63 N.E. 607, 609 (1902). Here, the Master Complaint contains sufficient allegations that support the claim that the CPM Defendants failed to exercise any or even very slight care when they decided to place their bottom line before their patients' health and safety. Plaintiffs allege that the CPM Defendants decided to purchase non-FDA approved preservative-free MPA from an unaccredited compounding facility with a known history of contamination issues to inject directly into their patients' vulnerable spinal cords through an epidural injection, without conducting any due diligence, because it was cheaper than the FDA approved steroid. *See* Master Compl., ¶¶ 192, 198-99, 204.

These circumstances and conditions are the type of class contemplated in *Johnson*, where ordinary negligence becomes gross negligence, as the Master Complaint specifically provides the following:

> 154. In many instances, the Clinic Related Defendants injected MPA directly into patients', including Plaintiffs', spinal canals so as to enter the central nervous system, bypassing many or all of the body's natural defensive mechanisms.
>
> 155. The Clinic Related Defendants knew, or should have known, that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion.
>
> 156. The Clinic Related Defendants knew, or should have known, that the MPA they purchased acts as an immune system-suppressing agent, thus weakening the patient's, including Plaintiffs', natural ability to fight off pathogens that could possibly be included in the injection.

See Master Compl. Due to the risks and complications associated with epidural steroid

injections, even FDA approved steroids note on their label that the steroid is not recommended for injection into the epidural space near the spine because of reports of serious medical events, including death associated with administering steroids in that fashion.[19] This type of critically important information was not shared with Plaintiff, Mr. Brady, prior to injecting contaminated MPA into the epidural space of his spine. Nor was he informed that there was a safer, FDA-approved alternative. The detailed averments above demonstrate that Plaintiffs have provided sufficient factual allegations to support their claim for gross negligence at this time. To dismiss this claim when Plaintiffs have only just begun to receive production from Defendants, would be unwarranted, premature and without merit.

III. Plaintiffs Set Forth Sufficient Allegations to State a Claim for Violations of Ohio's Consumer Sales Practices Act ("CSPA")[20]

Similar arguments attempting to escape liability and pigeon hole the Plaintiffs' consumer protection claim into one solely arising "in the context of the physician-patient relationship,"[21] have been over-ruled by this Court when declining to dismiss such a claim related to the Tennessee Clinic Defendants. As the Court appropriately points out, "the heart of plaintiffs…claims is not that the Tennessee Clinic Defendants failed to properly administer the MPA, but that they sold the MPA to plaintiffs on the basis of false and incomplete information…these allegations do not really pertain to the provision of healthcare services." The allegations are identical here as it related to Plaintiffs CSPA claim against CPM, and therefore, dismissal should be similarly denied.

Moreover, CPM Defendants completely disregard well-established Ohio law finding that

[19] David Armstrong, *Bristol-Myers Warning Ignored on Steroid Shots Tied to Deaths*, Bloomberg, January 25, 2012, http://www.bloomberg.com/news/2012-01-25/bristol-myers-warning-ignored-on-steroid-shots-tied-to-deaths.html.
[20] Plaintiffs concede dismissal of this Count against Dr. Gururau Sudarshan, as physicians are exempted from the CSPA.
[21] CPM Defendants' Motion, p. 9.

a hospital or health care facility can be held liable under CSPA given they are not specifically exempted by statute. *Elder v. Fischer*, 129 Ohio App.3d 209, 215, 717 N.E.2d 730, 734 (1st Dist.1998) ("…we conclude that had the legislature wanted to exclude from the purview of the CSPA residential-care facilities or any other businesses or professions, it only needed to have said so."); *Summa Health Sys. v. Vinigre*, 140 Ohio App. 3d 780, 795-96, 749 N.E.2d 344, 356 (2000) (holding "a transaction between a service provider such as a hospital and the consumer is not clearly exempted" from the CSPA). In *Monroe v. Forum Health*, the court found that a "consumer transaction" as it is defined in O.R.C. 1345.0 can include hospitals even as it relates to specific medical treatments and not just billing. See *Monroe v. Forum Health*, No. 2012-T-0206, 2012-Ohio-6133, slip op. at 10 (Ohio Ct. App. Dec. 24, 2012).

Plaintiffs have sufficiently stated allegations of violations of Ohio Consumer Sales Practices Act per O.R.C. 1345.01 plausible to entitle them to relief. *See* Master Compl., Count IV. CPM Defendants made representations to Plaintiff, Mr. Brady, that he was getting a safe and effective steroid. Furthermore, Plaintiffs allege that the CPM Defendants actually billed Plaintiff for the FDA approved Depo-Medrol, rather than the non-FDA approved compounded preservative-free MPA, which he actually received. Cincinnati Pain Management, Ltd., made inaccurate representations about the quality of the services it was offering and inappropriately billed Plaintiffs for an FDA approved drug, rather than the NECC contaminated drug they were actually getting. Consequently, Plaintiffs have sufficiently stated a claim against the Cincinnati Pain Management, Ltd. healthcare facility for a violation of the CSPA.[22] For these reasons,

[22] While *Walsh v. Erie Cnty. Dep't of Job & Family Servs.*, makes a distinction between a "hospital" as in Summa and a "group of doctors," the court denies defendants partial motion for summary judgment on this issue because it is not an issue that has been decided in the Northern District of Ohio. 240 F. Supp. 2d 731, 767-68 (N.D. Ohio 2003). As a result, since the CPM Defendants are attempting to dismiss the claim under 12(b)(6), a much lower burden than a motion for summary judgment under Fed. Civ. P. Rule 56, the CPM Defendants motion to dismiss should be denied and this question should be left to the trier of fact. *See id.*

Plaintiffs request this Court deny the CPM Defendants' motion to dismiss the violation of CSPA cause of action.

IV. Plaintiffs Properly Allege Violations of Ohio Products Liability Act ("OPLA")

A. Plaintiffs' Short Form Complaint Properly Alleges a Violation of OPLA through Incorporation of the Master Complaint and the Long Form Complaint

In seeking dismissal of Plaintiffs' OPLA claim, the CPM Defendants ignore entirely that Plaintiffs incorporated all facts and allegations set forth in the Long Form Complaint as well as Master Complaint into their short form complaint. Brady Short Form Compl. Dkt. No. 1:14-cv-10284-RWZ, Doc. No. 14, filed February 10, 2014. The Long Form Complaint sets forth over 20 separate paragraphs describing specific allegations of violations of the OPLA. *See* Long Form Complaint ¶¶ 155-177. The detailed allegations set forth in the Long Form Complaint are grounds alone to deny the CPM Defendants' motion. Moreover, Plaintiffs sufficiently pled facts alleging a violation of OPLA in the Master Complaint as well.

The CPM Defendants forget the usual MDL process and that the Master Complaint sets forth that it "is filed for administrative purposes only. It does not replace or supersede the complaints associated with existing civil actions." Master Compl., ¶ 9. In the normal course, master complaints are adopted by short form complaints, and long form complaints are drafted and filed when a case is selected for bellwether trial. This is the efficient way of moving cases forward in an MDL involving the potential application of laws of dozens of states, and in fact, the number of motions to dismiss filed in the MDL at this stage is unprecedented. The Master Complaint sets forth allegations meant to apply across fifty states, certainly it would have been unduly burdensome and unworkable for Plaintiffs to break down product liability law in every state involved in this tragedy in the Master Complaint.

Nonetheless, Plaintiffs sufficiently pled facts alleging a violation of OPLA in the Master

Complaint. The CPM Defendants disregard all the allegations actually made against Defendants in the Master Complaint, even if they were not specifically directed at the Ohio Products Liability Act. Also, the CPM Defendants fail to cite any case law to support their contention. Recognizing that Plaintiffs adopted Count IX, which sets forth allegations of violations of product liability law in Tennessee, CPM Defendants ignore entirely that the Ohio law is the same, i.e. that the CPM Defendants can be held liable if the Plaintiffs are "unable to enforce a judgment against a manufacturer of that product due to insolvency of the manufacturer. See O.R.C. § 2307.78(B)(2)." *See* CPM Brief p. 110-11; *see also* Master Complaint, Count IX.

Further, dismissal is not the appropriate remedy, rather Plaintiffs should have an opportunity to amend these claims to specifically name the OPLA in the Short Form Complaint if the Court deems it necessary at this early stage in spite of specific incorporation of detailed allegations set forth in the Plaintiffs' Long Form Complaint. *See EEOC v. Ohio Edison Co.,* 7 F.3d 541, 546 (6th Cir.1993) ("where a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district court dismisses the action with prejudice.") (*quoting Bank v. Pitt*, 928 F.2d 1108, 1112 (11th Cir.1991)); *see also Fisher v. Roberts*, 125 F.3d 974, 977-78 (6th Cir. 1997) ("We have recognized that it is necessary to permit the liberal amendment of complaints in order to adhere to 'the principle that cases should be tried on their merits rather than on the technicalities of pleading.'") (*quoting Janikowski v. Bendix Corp.*, 823 F.2d 945, 950 (6th Cir. 1987). For the reasons set forth above, CPM Defendants' motion should be denied.

B. CPM Defendants can be Liable as "suppliers" Under the OPLA for all Causes of Action

This Court should not deviate from its well-reasoned prior decision denying dismissal of

Plaintiffs' product liability claims.[23] When faced with similar arguments, this Court allowed Tennessee Plaintiffs to proceed with their products liability claims against the Tennessee Clinic Defendants, finding the "plaintiffs have adequately stated claims for relief" and that "plaintiffs may proceed with their products liability claims," despite the lack of legal precedent in Tennessee, which isn't an issue here.[24] Indeed, contrary to what the CPM Defendants would like the Court to believe, it is well-established under Ohio law, that hospitals are suppliers under the OPLA. In *Saylor v. Providence Hosp*., a hospital argued that it was not a "supplier" or "seller" under the OPLA of screws and plates that were negligently manufactured and inserted into plaintiff's skull. 113 Ohio App. 3d at 5-8. The hospital argued they could only be considered an "intermediary supplier," and therefore were not liable. *Id.* Notwithstanding this argument, and the statutory exclusion[25] relied upon by the CPM Defendants, the court disagreed and denied dismissal. *Id*. The *Saylor* court cited *Anderson v. Olmsted Util. Equip., Inc*., 60 Ohio St.3d 124, 127-129, 573 N.E.2d 626, 629-630 (1991), stating, "the Supreme Court of Ohio declined to limit supplier liability to an actual sale in the traditional sense, holding that the only relevant question was whether the "seller" facilitated placing the product into the stream of commerce." *Id.* at 5.

Clearly, as alleged, by purchasing the contaminated MPA from NECC and selling it to Plaintiff, Mr. Brady, and billing him and his insurer, CPM Defendants have facilitated placing the MPA into the stream of commerce. *See* Master Complaint, ¶¶ 319, 320, 333. Further, the court wrote, "Ohio's codification of products liability law is a continuum which follows the product. The consumer, in this case the patient, is at the least culpable end of the chain," just like the Plaintiffs here. *Id.* Therefore, the healthcare facility, and likely the physicians, is liable for facilitating the placement of NECC's contaminated MPA into the stream of commerce, injecting

[23] *See* Order 1360, p. 25-31.
[24] *See id.*, p. 30-31.
[25] O.RC. § 2307.71(A)(15)(b).

it into Plaintiff and billing him and his insurer for it.

As the CPM Defendants appropriately concede, suppliers can be held liable for the actions of the manufacturer if the claimant will not be able to recover because of insolvency on the part of the manufacturer, as it is in this case given that NECC is now insolvent. *See* O.R.C. § 2307.78(B)(2). For this reason alone, the OPLA count cannot be dismissed. This Court agreed when declining to dismiss the products liability claim against Tennessee Clinic Defendants where a similar statute is in play.[26] The Court should do the same here and deny dismissal given NECC's insolvency.

Moreover, suppliers can also be independently liable if: (a) the supplier was negligent and the negligence proximately caused the claimant harm; or (b) the product in question, when it left the supplier's control, did not conform to a representation made by the supplier and that representation and failure to conform proximately caused the claimant harm. *See* O.R.C. § 2307.78(A). As set forth herein the sections related to negligence and causation, the CPM Defendants were negligent and their negligence caused Plaintiffs' injuries making them liable under OPLA. Furthermore, the MPA did not conform with representations made by the CPM Defendants because it was not a safe product. Dismissing the above claims would be inappropriate given that all facts should be taken in the light most favorable to Plaintiffs and that they sufficiently pled allegations plausible to an entitlement of relief. Plaintiffs respectfully request this Court deny CPM Defendants' Motion to Dismiss their claims of violations of OPLA.

V. Plaintiffs' Complaint Sufficiently Sets Forth a Failure to Warn Claim

A. Plaintiffs' Failure to Warn Claim is Not Abrogated by the OPLA

Under very similar circumstances and facing the same arguments, this Court ruled that the Plaintiffs could proceed against the New Jersey Clinic Defendant with their failure to warn

[26] *See* Order 1360, p. 26, 30-31.

claims and considered them "separate and viable on their own" from the New Jersey Product Liability Act.[27] The same logic applies here where the CPM Defendants also claim the that Plaintiffs' failure to warn claim is abrogated by the OPLA. Indeed, the Court's acknowledgement of the allegations in the Master Complaint apply equally here; the claims are grounded in the CPM Defendants' "negligent performance of their medical services in obtaining and administering the MPA, not in the defectiveness of the MPA itself." The Court should not deviate from its previous, well-reasoned decision and hold that Plaintiffs' failure to warn claim not abrogated by the OPLA.

Like the New Jersey Clinic Defendant, in claiming that Plaintiffs' failure to warn claims are abrogated by the OPLA, CPM Defendants entirely ignore many allegations regarding their failure to warn that relate not to just the defective product, but also their failure to warn of several other things unrelated to the product, including, for example, failing to warn of the vulnerability of the central nervous system, their involvement in bulk purchasing, the existence of safer alternatives, and the use of an unaccredited compounding pharmacy as opposed to an FDA regulated manufacturer for creation of the product. *See* Master Compl., ¶¶ 154-156, 158, 161-163, 183, 232-234. As acknowledged by this Court when denying dismissal, Plaintiffs' also allege that the CPM Defendants "failed to perform necessary due diligence to determine safety and quality of NECC's drugs…failed to investigate whether NECC was a reputable and safe supplier…fail[ed] to properly inform patients about the 'true nature' of the drug, NECC, and the risks and dangers associated with the MPA's administration."[28] Indeed, many of Plaintiffs' other allegations of "failure to warn" at common law are based on a "lack of informed consent" due to the conduct of the CPM Defendants. *See* Master Compl., ¶302. In Ohio, courts have equated a

[27] *See* Order 1360, p. 52-55.
[28] *See id.* at p. 53.

"failure to warn" claim against a doctor to a "lack of informed consent claim." *See Saxe v. United States*, 577 F. Supp. 135, 146 (N.D. Ohio 1983) aff'd, 751 F.2d 386 (6th Cir. 1984). Informed consent requires disclosure of material risks and dangers inherently and potentially involved, as well as any alternatives. *Siegel v. Mt. Sinai Hosp. of Cleveland*, 62 Ohio App.2d 12, 21, 403 N.E.2d 202, 209 (1978). These allegations obviously relate to Defendants' conduct and their malpractice and not the product and therefore, are not abrogated.

Notably, CPM Defendants cannot have it both ways – either Plaintiffs have a valid OPLA claim or they do not. And if not, the common law failure to warn claim cannot be subsumed by the OPLA and it stands on its own unaffected by it. Moreover, "[t]he supplier may be held independently liable for misrepresentations or negligence. This includes failure to warn or inadequate warnings." *Saylor*, 113 Ohio App. 3d at 5-8. Nonetheless, Plaintiffs have pled sufficient facts related to the CPM Defendants' failure to warn, not only about the contaminated MPA, but other critical information not product based. Therefore, dismissal should be denied.

B. Plaintiffs' Complaint which Incorporates the Master and Long Form, Adequately Allege All Elements of a Common Law Failure to Warn Claim

This Court has also allowed plaintiffs with identical failure to warn claims against New Jersey and Tennessee Clinic Defendants to proceed based upon the same allegations set forth in the Master Complaint.[29] The Court should likewise deny CPM's motion and allow Plaintiffs to proceed on their failure to warn count. Like the New Jersey and Tennessee Clinic Defendants, the CPM Defendants ignore many claims in the Master Complaint and Long Form Complaint, that were adopted and incorporated by reference in Plaintiffs' Short Form Complaint, which establishes that Plaintiffs sufficiently pled all of the elements of a failure to warn claim. Each and every allegation the CPM Defendants claim are missing are actually in the Master Complaint, as

[29] *See id.* at pp. 36 and 52-55.

set forth in the paragraphs below in bold in Count VIII – Failure to Warn:

> 301. **The Clinic Related Defendants failed to inform their patients, including Plaintiffs, that they were being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer**.
>
> 302. Many, if not all, of the Clinic Related Defendants prepared a Consent for Treatment Form. The form, which was presented to Plaintiffs by the Clinic Related Defendants, and which Plaintiffs read and relied upon when agreeing to accept treatment, failed to inform the Plaintiffs of the risks and benefits of the procedures before it was performed. When presenting the form to Plaintiffs, the Clinic Related Defendants knew that nobody on its behalf would be informing Plaintiffs of the inferior and unreasonably dangerous nature of the NECC drug that would be administered to Plaintiffs. Clinic Related Defendants knew that **if Plaintiffs were informed of the true nature of the NECC drugs, Plaintiffs would decline treatment with NECC drugs, threatening the Healthcare Providers' profits.**
>
> 303. As a proximate result of the Clinic Related Defendants' wrongful conduct, Plaintiffs suffered grievous bodily injury and/or death, have required extensive medical treatment, have incurred and in the future will incur substantial medical bills and have suffered and will in the future suffer inconvenience and severe mental anguish.

See Master Compl. ¶¶ 301-303.

Thus, the detailed averments above demonstrate that the Master Complaint provides sufficient factual allegations to support Plaintiffs' claims for failure to warn/lack of informed consent in Count VIII. Moreover, whether the CPM Defendant's appropriately warned Plaintiff is a question of fact. *Wells v. Van Nort* (1919), 100 Ohio St. 101, 125 N.E. 910; *see also Guth v. Huron Rd. Hosp*., 43 Ohio App. 3d 83, 86, 539 N.E.2d 670, 673-74 (1987) ("Without recourse to expert testimony…these issues are not appropriately resolved through the granting of appellees' motions for summary judgment."). Dismissal of this claim is improper and premature.

VI. Allegations Against Defendants are Sufficient to Sustain a Claim For Punitive Damages in Ohio

As previously decided by this Honorable Court when facing the same arguments related

to identical allegations against the New Jersey Clinic, Plaintiffs' punitive damages claim cannot be dismissed at this time.[30] This Court acknowledged that the "Plaintiffs do make various assertions in the complaint that the [Defendants] actions 'went beyond mere thoughtlessness, inadvertence or error of judgment'" and "also allege that [Defendants] willfully and knowingly failed to abide by consumer safety regulations and withheld important safety information from patients."[31] The Court concluded, as it should here, that "[s]uch allegations are enough to sustain plaintiffs' punitive damages claims at this early stage."[32]

Indeed, Plaintiffs' allegations sufficiently state a claim for punitive damages. Plaintiffs must simply plead the actions go beyond mere negligence so as to rise to the level as "a conscious disregard for the rights and safety of other persons that has a great probability of causing substantial harm." *See Preston v. Murty*, 32 Ohio St.3d 334, 335, 512 N.E.2d 1174, 1175-1176 (1987). Despite the CPM Defendants' contentions, Plaintiffs have more than sufficiently pled CPM Defendants' actions represent a conscious disregard for the rights and safety of other persons that has a great probability of causing and did cause substantial harm. In fact, with respect to Defendants' conduct, the Master Complaint states in pertinent part:

> 237. The foregoing acts and omissions by the Clinic Related Defendants went beyond mere thoughtlessness, inadvertence or error of judgment.
>
> 238. The actions of the Clinic Related Defendants did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including Plaintiffs.
>
> 239. The acts and omissions of the Clinic Related Defendants constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Plaintiffs.
>
> * * *

[30] *See* Order 1360, p. 62.
[31] *Id.*
[32] *Id.*

> 249. Clinic Related Defendants ***willfully and knowingly*** failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the consumer protection statutes set forth herein.
>
> 250. Clinic Related Defendants' ***willful and knowing*** withholding of important safety information and critical product information constitutes a violation of various state consumer protection statutes set forth herein.
>
> 251. Clinic Related Defendants ***actively, knowingly, and deceptively*** concealed the product's dangerous properties and life-threatening risks of which they knew or should have know [sic]. This conduct evidences bad faith and unfair and deceptive practices.

(See Master Compl., ¶¶ 237-251).

The Court should not upset its well reasoned decision denying dismissal of this claim. As recognized by the Court, a claim for punitive damages should be evaluated at the end of the discovery period when all information discoverable has been disclosed to both parties. Because Plaintiffs have alleged that Defendants' actions were "willful" and "knowing," and because such conduct went beyond mere assertions of negligence so as to create a "conscious disregard for safety," Plaintiffs have adequately and sufficiently stated a claim for punitive damages in Ohio. Furthermore, dismissal of this action would be premature as Plaintiffs have not had the benefit of discovery to fully develop their cause of action. In the alternative, should this Court find the pleadings somehow deficient, Plaintiffs should be granted leave to amend their complaints.

VII. Plaintiffs Should be Provided the Opportunity to Amend their Complaint

Even assuming, *arguendo*, that this Court concludes that the factual allegations against the CPM Defendants were inadequately pleaded, the Federal Rules of Civil Procedure direct courts to freely provide the opportunity to amend a complaint: "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a). If a complaint is subject to dismissal per Fed. R. Civ. P. 12(b)(6), leave should be given to amend unless doing so would be futile or cause undue delay. *See Steir v. Girl Scouts of the USA*, 383 F.3d 7, 12 (1st Cir. 2004). If leave to amend is sought before discovery, "amendment is not deemed futile as long as the proposed

amended complaint sets forth a general scenario which, if proven, would entitle the plaintiff to relief against the defendant n some cognizable theory." *Hatch v. Dep't for Children, Youth & Their Families*, 274 F.3d 12, 19 (1st Cir. 2001). The complaint in the case at bar is not tainted with either futility or undue delay and Plaintiffs ask that this Honorable Court provide an opportunity to amend their complaint should the Court deem it necessary.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court deny the CPM Defendants' Motion to Dismiss in its entirety. In the alternative, should this Court determine that Plaintiffs' allegations are deficient, Plaintiffs respectfully request the opportunity to amend their complaint to address any shortcomings.

Date: October 17, 2014

Respectfully Submitted,

Plaintiffs Joseph and Rebecca Brady,

/s/ Kimberly A. Dougherty

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CERTIFICATE OF SERVICE

I, Kimberly A. Dougherty, hereby certify that I caused a copy of the above *Plaintiffs' Memorandum of Law in Opposition to CPM Defendants' Motion to Dismiss Pursuant to F.R.C.P. 12(b)(6)* pursuant to Local Rule 7.1(b)(4) to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: **October 17, 2014**

/s/ Kimberly A. Dougherty
Kimberly A. Dougherty, Esq.